

**DETAILED ACTION**

This is the second Office Action based on the 10/679628 application filed September 29, 2003. Claims 12-17 as newly presented are currently pending and considered below.

***Response to Amendment***

1. In light of the amendment made by applicant, the examiner has removed the previous objection to the Abstract. Further, in light of the cancelling of claims 1-11, the examiner has removed all prior claim objections.

***Claim Objections***

2. Claim 12 is objected to because of the following informalities: in line 14, "chanmber" should read -chamber--.
3. Claim 17 is objected to because of the following informalities: in line 4, "discharrge" should read -discharge--.
4. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The preamble of the claim says that the two products are delivered "simultaneously" but lines 4-5 of the claim provide for means to expel the products "simultaneously or successively". Clarification is requested.

8. Line 5 of the claim contains the phrase "said means", however, it is not clear whether this is directed to the aforementioned "means designed to receive two or more different products" or "means designed to expel said products simultaneously or successively". For purposes of examination, and based on the identification numbers used with reference to the figures, the examiner has interpreted the "said means" to be drawn to the "means designed to receive two or more different products".

9. Line 10 of the claims contains the phrase "the anterior wall" of the cannula, but there is no direction as to which end of the cannula is "anterior" and which is "posterior". For purposes of examination, the examiner has interpreted the anterior end to be the one away from the dispensing orifice.

#### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 4,421,504 to Kline.

Regarding the above claims, Kline discloses a disposable cannula (77) designed to simultaneously deliver products of different compositions (84, 85) comprising means to receive two or more different products (78), and means to expel said products (91), said receiving means comprising a barrel (78) defining a single cylindrical chamber (86) designed to receive and retain a first product (84), said chamber having a plurality of holes (80) in correspondence with the distal section of said cannula (Fig. 21), to allow expulsion of the first product; an opening in the anterior wall of the cannula (86) provided with means (87) to receive and retain a second product (85), the means for expelling comprising a plunger (91) designed to press on the first product (via second product 85) to cause its expulsion, and a sealed separator (83) in said chamber downstream of said plunger and slidably therein, said separator provided with means designed to engage and control the expulsion of said second product (membrane separates the first and second product until forced to rupture by plunger 91). Further, Kline discloses a sheath (82) covering at least the length of the cannula containing the openings (Fig. 21), that ridges (the examiner notes that attachment of septum 83 to cavity 86 would create a ridge) retain separator 83 in position, that the inner wall of the cannula is provided with ridges (87) to retain the second product in position (the examiner notes that the membrane itself is one ridge), and that the inner surface of the cannula is provided with means for retaining the plunger in position prior to use (88). Finally, Kline discloses a dispenser with holes (21) along its full length (Fig. 7) which

could be used in concert with the products (84 and 85) and the plunger (91) in order to expel air prior to injection.

***Response to Arguments***

12. Applicant's arguments with respect to claims 12-17 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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